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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

| EXAMINER | |
|---|---|
| NAJARIAN, LENA | |
| **ART UNIT** | **PAPER NUMBER** |
| 3626 | |

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/844,195 | GOETZKE ET AL. | |
| | Examiner | Art Unit | |
| | Lena Najarian | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 April 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☒ Claim(s) *10 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20010601*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



EA

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13, and 15-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 13-28 of copending Application No. 09/844,234. Although the conflicting claims are not identical, they are not patentably distinct from each other because "identifying individuals at risk for chronic pain condition in a population" is considered by the Examiner to be a form of "risk stratification of potential chronic pain patients in a population".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Oath/Declaration*

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It was not executed in accordance with either 37 CFR 1.66 or 1.68.

### *Specification*

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because its length exceeds 150 words. Correction is required. See MPEP § 608.01(b).

### *Claim Objections*

4. Claims 10 and 27 are objected to because of the following informalities:

"monitored and for changes" should be changed to "monitored for changes" in line 1 of claim 10. Also, in line 4 of claim 27, "causes the computer access" should be changed

to "causes the computer to access" and "applying" in line 10 should be changed to "apply". Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

5. Claims 1-26 and 29-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

(A) In the present case, claims 1-25 only recite an abstract idea. The recited steps of exemplary claim 1 of merely selecting direct medical indicia, selecting indirect medical indicia, selecting non-medical indicia, selecting a chronic pain indication that serves as a dependent variable, creating a chronic pain model, applying the chronic pain model to a population, and identifying potential chronic pain patients does not apply, involve, use,

or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention identifies individuals at risk for chronic pain in a population. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-25 are deemed to be directed to non-statutory subject matter.

(B) In the present case, claim 26 only recites an abstract idea. The recited steps of merely accessing a chronic pain model, applying the chronic pain model to a population, identifying potential chronic pain patients, establishing categorization preferences, calculating the categorization preferences, categorizing each potential chronic pain patient, and monitoring the potential chronic pain patient's indicia does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention identifies and categorizes potential chronic pain patients. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 26 is deemed to be directed to non-statutory subject matter.

(C) Moreover, in the present case, claims 29-30 only recite an abstract idea. The recited steps of exemplary claim 29 of merely comparing the identified chronic pain patients with outside diagnosed chronic pain patient data to create a patient error list, applying an error assessment model, applying a sensitivity model, selecting at least one patient indicia change from the potential patient indicia changes, and modifying the patient indicia does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a sensitivity analysis of a chronic pain patient model. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 29-30 are deemed to be directed to non-statutory subject matter.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 6-7, 9-16, 21-22, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (6,110,109) in view of Comanor et al. (5,860,917).

(A) Referring to claim 1, Hu discloses a method for identifying individuals at risk for a condition in a population, comprising (see abstract of Hu):

selecting direct medical indicia associated with a condition that serve as independent variables (col. 2, lines 4-20 of Hu);

selecting indirect medical indicia associated with a condition that serve as independent variables (col. 2, lines 4-20 of Hu);

selecting non-medical indicia associated with a condition that serve as independent variables (col. 2, lines 4-20 of Hu);

selecting a condition indication that serves as a dependent variable (col. 1, lines 43-61 of Hu);

creating a model using direct medical indicia, indirect medical indicia, non-medical indicia, and a condition indication (col. 1, lines 43-61 of Hu);

applying the model to a population to create a patient mathematical expression for each member of the population (Fig. 1 of Hu); and,

identifying potential patients by comparing each patient mathematical expression to selection objectives (Fig. 1 of Hu).

Hu does not specifically disclose the application of the model to a chronic pain condition.

However, Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so

would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(B) Referring to claim 2, Hu discloses wherein the model comprises a logic structure to define a logical decision process to operate on the independent variables and to progressively reach greater certainty about potential patients (col. 1, lines 42-61 and col. 2, lines 4-20 of Hu); weighted variables to reflect greater relevance of certain direct medical indicia, indirect medical indicia, and non-medical indicia to the indication (see column 9 of Hu); and, equations that represent relationships between or among weighted variables to form an inference engine (see column 10 of Hu).

Hu does not specifically disclose a chronic pain condition.

However, Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(C) Referring to claim 3, Hu discloses a condition inference engine that comprises dependent variables, independent variables, and equations (col. 4, lines 11-51 of Hu).

Hu does not disclose that the condition is chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

Hu does not specify a minimum number of variables and equations.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to accommodate the needs of the user conducting a study with large sets of data. The motivation for doing so would have been for a more accurate model.

(D) Referring to claim 6, Hu discloses wherein the weighted variables are developed using logistical regression to establish relationships between the dependent variable and independent variables (col. 12, lines 7-47 of Hu).

(E) Referring to claim 7, Hu does not expressly disclose wherein the weighted variables are developed using discriminate analysis to establish relationships between the dependent variable and independent variables.

Comanor discloses wherein the weighted variables are developed using discriminate analysis to establish relationships between the dependent variable and independent variables (see column 10 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Comanor within Hu. The motivation for doing so would have been to predict the likely responses of patients (col. 6, lines 47-50 of Comanor).

(F) Referring to claim 9, Hu discloses wherein the potential patients are identified with a patient mathematical expression generated by the inference engine operating on the patient indicia and the condition indication (col. 1, lines 42-61 of Hu).

Hu does not disclose that the condition is chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(G) Referring to claim 10, Hu discloses wherein the patient indicia are monitored and for changes and the patient mathematical expression is updated when patient indicia change (col. 2, lines 38-57 of Hu).

(H) Referring to claim 11, Hu does not disclose wherein the patient mathematical expression is used to administratively categorize potential chronic pain patients.

Comanor discloses wherein the patient mathematical expression is used to administratively categorize potential chronic pain patients (col. 3, lines 1-10 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Comanor within Hu. The motivation for doing so would have been to effectively classify individuals (col. 3, lines 1-10 of Comanor).

(I) Referring to claim 12, Hu discloses wherein the categories are selected from the group consisting of positive-in, positive-out, probable-in, and probable-out (col. 2, lines 48-57 of Hu).

(J) Referring to claim 13, Hu discloses establishing categorization preferences that specify patient characteristics that are desired to be selected (col. 2, lines 38-57 of Hu); calculating the categorization preferences with each potential patient's mathematical expression to identify relationships between the categorization preferences and each potential patient's mathematical expression (col. 1, lines 42-61 of Hu); and, categorizing each potential patient based upon the relationships between the categorization preferences and each potential patient's mathematical expression (col. 3, lines 18-56 of Hu).

Hu does not disclose a chronic pain patient.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(K) Referring to claim 14, Hu does not disclose wherein the selection objectives are selected from the group consisting of potential chronic pain patients with pain attributable to their work environment, potential chronic pain patients unlikely to be compliant with treatment therapy, potential chronic pain patients unlikely to return to

work, potential chronic pain patient suitable for low cost therapy, and potential chronic pain patient treatable by a primary care clinician.

Comanor discloses potential chronic pain patient treatable by a primary care clinician (col. 1, lines 46-52 of Comanor). Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to determine a successful treatment regimen for a patient afflicted with a disease (col. 1, lines 46-52 of Comanor).

(L) Referring to claim 15, Hu does not disclose wherein the direct medical indicia are related to chronic pain in a known medical manner and recorded by a clinician.

Comanor discloses wherein the direct medical indicia are related to chronic pain in a known medical manner and recorded by a clinician (col. 15, lines 58-62 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Comanor within Hu. The motivation for doing so would have been to choose common variables for use in the models (col. 15, lines 58-62 of Comanor).

(M) Referring to claim 16, Hu does not disclose wherein the direct medical indicia are independent variables selected from the group consisting of primary diagnosis, associated secondary diagnosis, co-morbidities, drug treatment regimen, telephone

consultations with a clinician, trauma episodes, palliative care, rehabilitative care, clinician office visits, emergency room visits, and hospitalizations.

Comanor discloses clinician office visits (col. 5, lines 20-37 of Comanor). Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to use data gathered from direct examinations (col. 5, lines 29-31 of Comanor).

(N) Referring to claim 21, Hu discloses wherein the non-medical indicia are independent variables, such as smoking status (col. 2, lines 8-11 of Hu). Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(O) Referring to claim 22, Hu discloses wherein a source for non-medical indicia is patient surveys (col. 10, lines 40-46 of Hu). Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(P) Referring to claim 25, Hu discloses wherein the patient population is selected from a clinician database (col. 2, lines 38-57 of Hu). Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(Q) Referring to claim 26, Hu discloses a method for identifying and categorizing potential patients, comprising (see abstract of Hu):

accessing a model having direct medical indicia, indirect medical indicia, non-medical indicia, and an indication that are arranged logic structure, with weighted variables, and equations representing relationship between or among the variables (col. 1, lines 42-61, col. 2, lines 4-20, and col. 9 of Hu);

applying the model to a population to create a patient mathematical expression for each member of the population (col. 1, lines 13-28 and Fig. 1 of Hu);

identifying potential patients by comparing each patient mathematical expression to selection objectives (col. 1, lines 42-61 of Hu);

establishing categorization preferences that specify characteristics of patents that are desired to be categorized (col. 2, lines 38-57 of Hu);

calculating the categorization preferences with each potential patient's mathematical expression to identify relationships between the categorization preferences and each potential patient's mathematical expression (col. 1, lines 42-61 of Hu);

categorizing each potential patient based upon the relationships between the categorization preferences and each potential patient's mathematical expression (col. 3, lines 18-56 of Hu);

and, monitoring the potential patient's direct medical indicia, indirect medical indicia, and non-medical indicia for changes and updating the patient's mathematical expression based upon changes to the potential patient's direct medical indicia, indirect medical indicia, and non-medical indicia (col. 2, lines 38-57 of Hu).

Hu does not expressly disclose that the patients have chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(R) Referring to claim 27, Hu discloses a computer software product that includes a medium readable by a computer, the medium having stored thereon instructions for identifying patients in a population having a condition, comprising (col. 19, lines 21-36 and abstract of Hu):

a first set of instructions when executed by the computer, causes the computer to access a model having direct medical indicia, indirect medical indicia, non-medical indicia, and a indication that are arranged logic structure, with weighted variables, and equations representing relationship between or among the variables (col. 1, lines 42-61, col. 2, lines 4-20, and col. 9 of Hu);

a second set of instructions when executed by the computer, causes the computer to apply the model to a population to create a patient mathematical expression for each member of the population (col. 1, lines 13-28 and Fig. 1 of Hu);

and, a third set of instructions when executed by the computer, cause the computer to identify potential patients by comparing each patient mathematical expression to selection objectives (col. 1, lines 42-61 of Hu).

Hu does not expressly disclose that the patients have chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(S) Referring to claim 28, Hu discloses a fourth set of instruction when executed by the computer, cause the computer to establish categorization preferences that specify characteristic of patents that are desired to be categorized (col. 2, lines 38-57 of Hu);

a fifth set of instruction when executed by the computer, cause the computer to calculate the categorization preferences with each potential patient's mathematical expression to identify relationships between the categorization preferences and each potential patient's mathematical expression (col. 1, lines 42-61 of Hu); and,

a sixth set of instruction when executed by the computer, cause the computer to categorize each potential patient based upon the relationships between the categorization preferences and each potential patient's mathematical expression (col. 3, lines 18-56 of Hu).

Hu does not expressly disclose that the patients have chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Hu. The motivation for doing so

would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

8. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (6,110,109) in view of Comanor et al. (5,860,917) as applied to claims 1 and 2 above, and further in view of Goldman et al. (US 2001/0054032 A1).

(A) Referring to claims 4 and 5, Hu and Comanor do not disclose wherein the logic structure is developed using Chi-Square Automatic Interaction Detection (CHAID) analysis to establish relationships between a dependent variable and independent variables and wherein the logic structure is developed using Classification Adjusted Regression Tree (CART) analysis to establish relationships between the dependent variable and the independent variables.

Goldman discloses the use of Chi-Square Automatic Interaction Detection (CHAID) analysis and Classification Adjusted Regression Tree (CART) analysis to establish relationships between the dependent variable and the independent variables (para. 118 of Goldman).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Goldman within Hu and Comanor. The motivation for doing so would have been to use a known statistical mechanism to determine correlations among data (para. 118 of Golman).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (6,110,109) in view of Comanor et al. (5,860,917) as applied to claims 1 and 2 above, and further in view of Blum et al. (5,500,343).

(A) Referring to claim 8, Hu and Comanor do not disclose wherein appropriateness of patient indicia is evaluated using the Hosmer-Lemeshow Goodness of Fit Analysis.

Blum discloses using the Hosmer-Lemeshow Goodness of Fit Analysis (col. 57, lines 31-42 of Blum).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Blum within Hu and Comanor. The motivation for doing so would have been to determine whether the model fits the data reasonably well (col. 57, lines 31-42 of Blum).

10. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (6,110,109) in view of Comanor et al. (5,860,917) as applied to claims 1 and 15 above, and further in view of Wong et al. (5,976,082).

(A) Referring to claim 17, Hu and Comanor do not disclose wherein the sources for direct medical indicia are selected from the group consisting of claims records, medical records, workers' compensation records, and employer records.

Wong discloses wherein the sources for direct medical indicia are selected from the group consisting of claims records, medical records, workers' compensation records, and employer records (col. 3, lines 49-60 of Wong).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Wong within Hu and Comanor. The motivation for doing so would have been for a comprehensive source of information (col. 3, lines 58-60 of Wong).

(B) Referring to claim 18, Hu and Comanor do not disclose wherein indirect medical indicia are a chronic pain co-morbidity that is recorded by a clinician.

Wong discloses wherein indirect medical indicia are a chronic pain co-morbidity that is recorded by a clinician (col. 12, lines 46-59 of Wong).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Wong within Hu and Comanor. The motivation for doing so would have been to include several independent variables of interest (col. 12, line 47 of Wong).

(C) Referring to claim 19, Hu discloses wherein the indirect medical indicia are independent variables selected from the group consisting of mental health condition, acute respiratory episodes, diabetes, and heart failure (col. 2, lines 8-11 of Hu).

(D) Referring to claim 20, Hu discloses wherein the sources for indirect medical indicia are selected from the group consisting of claims records, medical records, workers' compensation records, employer records, and patient surveys (col. 10, lines 40-46 of Hu).

11. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (6,110,109) in view of Comanor et al. (5,860,917) as applied to claim 1 above, and further in view of Grouhel et al. (US 6,353,024 B1).

(A) Referring to claims 23 and 24, Hu and Comanor do not disclose wherein the chronic pain indication is selected from the group consisting of Peripheral Neuropathy; Stump Pain; Phantom Pain; Complex Regional Pain Syndrome Type I (Reflex Sympathetic Dystrophy); Complex Regional Pain Syndrome Type II (Causalgia); Central Pain; Rheumatoid Arthritis; Osteoarthritis; Sickle Cell Arthropathy; Stiff Man Syndrome; Osteoporosis; Guillain-Barre Syndrome; Superior Pulmonary Sulcus Syndrome (Pancoast Tumor); Pain of Skeletal Metastatic Disease of the Neck, Arm, or Shoulder Girdle; Carcinoma of Thyroid; Post Herpetic Neuralgia; Syphilis (Tabes Dorsalis and Hypertrophic Pachymeningitis); Primary Tumor of a Vertebral Body; Radicular Pain Attributable to a Prolapsed Cervical Disk; Traumatic Avulsion of Nerve Roots; Primary Tumor of a Vertegral Body; Radicular Pain Attributable to a Thoracic Disk; Chemical Irritation of the Brachial Plexus; Traumatic Avulsion of the Brachial Plexus; Postradiation Pain of the Brachial Plexus; Painful Arms and Moving Fingers; Brachial Neuritis (Brachial Neuropathy, Neuralgic Amyotrophy, Parsonage-Turner Syndrome); Raynaud's Disease; Raynaud's Phenomenon; Frostbite and Cold Injury; Brythema Pernio (Chilblains); Acrocyanosis; Livedo Reticularis; Volkmann's Ischemic Contracture; Thromboangiitis; Intermittent Claudication; Rest Pain; Gangrene Due to Arterial Insufficiency; Other Postinfectious and Segmental Peripheral Neuralgia; Angina Pectoris; Postmastectomy Pain Syndrome (Chronic Nonmalignant); Late

Postmastectomy Pain or Regional Carcinoma; Segmental or Intercostal Neuralgia; Chronic Pelvic Pain Without Obvious Pathology; Pain from Urinary Tract; Carcinoma of the Bladder; Lumbar Spinal or Radicular Pain after Failed Spinal Surgery; Spinal Stenosis (Cauda Equina Lesion); Pain referred from Abdominal or Pelvic Viscera or Vessels Perceived as Sacral Spinal Pain; Femoral Neuralgia; and, Sciatica Neuralgia and wherein the source for chronic pain indications is the International Association for the Study of Pain (IASP) chronic pain guidelines.

Grouhel discloses various pain-related conditions, such as osteoarthritis and the International Association for the Study of Pain (col. 4, line 59 – col. 5, line 25 of Grouhel).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Grouhel within Hu and Comanor. The motivation for doing so would have been to have a comprehensive list of chronic pain conditions and to identify those conditions where pain persists beyond normal healing time (col. 5, lines 1-8 of Grouhel).

12. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al. (US 6,248,063 B1) in view of Comanor et al. (5,860,917).

(A) Referring to claim 29, Barnhill discloses a method for sensitivity analysis of a patient model, comprising (col. 25, line 65 – col. 26, line 5 of Barnhill):

comparing the identified patients with outside diagnosed patient data to create a patient error list (col. 18, line 44 – col. 19, line 23 and Fig. 16 of Barnhill);

applying an error assessment model to the patient error list to identify the non-corresponding patient indicia that contributed to the errors (col. 7, line 62 – col. 8, line 11 of Barnhill);

applying a sensitivity analysis model to the non-corresponding patient indicia to identify potential patient indicia changes to reduce errors in identifying patients; selecting at least one patient indicia change from the potential patient indicia changes to apply to the patient indicia; and, modifying the patient indicia with the at least one selected patient indicia change (col. 25, line 54 – col. 26, line 14 and col. 18, line 44 – col. 19, line 9 of Barnhill).

Barnhill does not expressly disclose that the patients have chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Barnhill. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

(B) Referring to claim 30, Barnhill discloses applying a sensitivity analysis model to the weighted variables to identify potential weighted variable changes to reduce errors in identifying patients; selecting at least weighted variable change from the potential weighted variable changes to apply to the weighted variables; and, modifying weighed variables to reflect greater or lesser relevance of patient indicia to reduce errors in

identifying patients (col. 25, line 54 – col. 26, line 14 and col. 18, line 44 – col. 19, line 9 of Barnhill).

Barnhill does not expressly disclose that the patients have chronic pain.

Comanor discloses the condition of chronic pain and statistical models (see abstract and col. 5, lines 7-11 of Comanor).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Comanor within Barnhill. The motivation for doing so would have been to produce robust, statistically significant models that assist clinicians in determining therapies (see abstract of Comanor).

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and apparatus for analyzing a patient medical information database to identify patients likely to experience a problematic disease transition (US 2002/0099686 A1); a healthcare management system and method of predicting high utilizers of healthcare services (US 2003/0195772 A1); a diagnostic system utilizing a Bayesian network model having link weights updated experimentally (6,076,083); a method of modifying comparable health care services (5,724,379); and monitoring an EEG (5,816,247).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

In
9-19-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600